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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,641	02/22/2002	Patrick A. Haverkost	BSI-486US	2371

7590 06/05/2009
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EXAMINER

LANG, AMY T

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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06/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/081,641	Applicant(s) HAVERKOST ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-33,47,48,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 9,12-16,18-29,48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10, 11, 17, 30-33, 47, and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/18/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/26/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

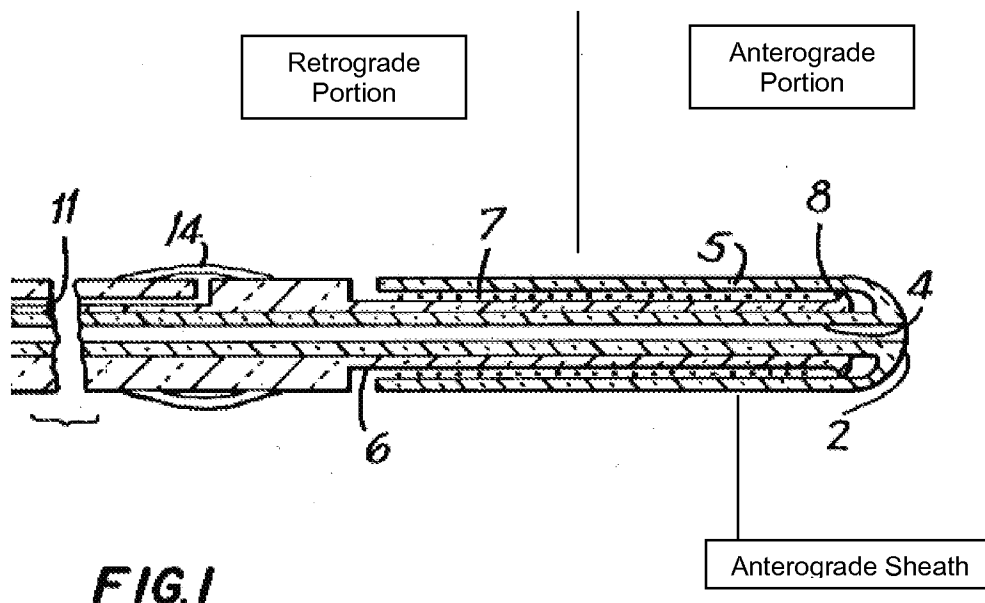
3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. **Claims 1, 3-5, 10, 11, and 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton et al. (US 5,078,720) in view of Abrams et al. (US 2003/0050684).

With regard to **claims 1, 3, 5, and 47**, Burton et al. (hereinafter Burton) discloses an introducer (see entire document) comprising a stent (7) mounted concentrically over a shaft (1, 4) having a distal tip (Figure 1). Inner sheath (6) is mounted concentrically over the shaft (Figure 1). Sleeve (5) is mounted over the shaft and stent to maintain the stent in a compressed configuration (column 4, lines 33-34). As shown below the sleeve further comprises an antegrade portion and a retrograde portion and comprises an antegrade sheath in the antegrade portion. The antegrade sheath is attached to a distal tip (2) and is moved distally to unsheath the portion of the stent that is contained thereunder (column 3, lines 44-54).



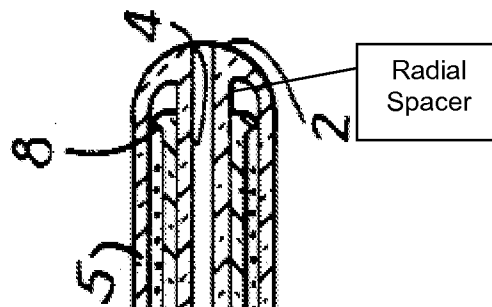
However, Burton does not specifically disclose an anchoring means. Burton though does teach the stent as a self expanding stent (column 1, line 9) and Abrams et al. (hereinafter Abrams) teaches that self expanding stents and balloon expandable stents are both well known in the art and interchangeable ([0002]). Therefore, it would have been obvious at the time of the invention to one of ordinary skill in the art for the stent of Burton to be expandable by a balloon. The balloon would then lie radially under the stent as is well known in the art.

The balloon of Burton in view of Abrams would anchor and engage the stent during proximal expansion of the Burton stent and therefore overlaps the instantly claimed anchoring means. Specifically, since the stent of Burton is expanded in a retrograde manner, the proximal end is released from the sleeve first. Therefore, the balloon expandable stent of Burton in view of Abrams allows the proximal end to be released first so that the balloon anchors the proximal end of the stent while the sleeve is still unsheathing the distal end of the stent.

Additionally, the instant claims use the phrase "for engaging and anchoring" with respect to the anchoring means which is not given full patentable weight. As long as the prior art meets the structural requirements and is capable of performing the functions, the prior art meets the limitations. In the instant case, the balloon of Burton in view of Abrams meets all the structural requirements and is capable of performing the intended function.

With regard to **claim 4**, the inner sheath of Burton defines a lumen. It is well known in the art for balloons to be inflated with a fluid running through an inner shaft.

With regard to **claims 10 and 11**, the portion shown below of the distal tip provides sufficient space between the inner sheath and anterograde sheath to contain the stent and is attached to the remaining portion of the distal tip. Therefore, the portion shown below overlaps the instantly claimed radial spacer.



5. **Claims 6, 30-33, and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton (US 5,078,720) in view of Abrams (US 2003/0050684) and Fiedler (US 5,817,101).

With regard to **claims 6, 30, and 33**, Burton in view of Abrams discloses the invention substantially as claimed wherein an outer sleeve is distally retracted to release the stent in a retrograde manner. However, Burton does not specifically disclose the sleeve as comprising a distinct and separate anterograde sheath and a retrograde sheath.

Fiedler teaches that a stent can be released in a retrograde manner or in a medial manner wherein the outer sleeve retracts proximally and distally to release the stent from a central location (column 4, lines 17-20). Therefore both methods are well known in the art and interchangeable so that it would have been obvious at the time of

the invention for Burton to use a medial stent release approach instead of a retrograde approach. This would release the stent in the same efficient manner and overlap the claimed anterograde sheath and retrograde sheath.

With regard to **claims 31, 30, and 51**, although Fiedler does not specifically disclose the anterograde sheath as longer than the retrograde sheath or where the two sheaths initially overlap, such modifications would involve a mere change in size. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Therefore, one sheath would be longer than the other or both sheaths would be longer and abut or overlap each other.

6. **Claims 7, 8, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton (US 5,078,720) in view of Abrams (US 2003/0050684), Fiedler (US 5,817,101), and Zadno-Azizi et al. (US 6,022,336).

Burton in view of Abrams and Fielder discloses the invention substantially as claimed wherein a stent is constrained by an anterograde and a retrograde sheath. However, Burton does not disclose a medial sheath located between the inner sheath and the retrograde sheath.

Zadno-Azizi et al. (hereinafter Zadno-Azizi) teaches that a reinforcing layer, specifically a metal braid, is well known in the art to provide increased stiffness (column 9, lines 51-59). It is the examiner's position that such a reinforcing layer overlaps the instantly claimed sheath. It is further the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention for the introducer of

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Burton to comprise an additional layer of a braided metal sheath between the inner sheath and retrograde sheath to provide increased stiffness.

Since Zadno-Azizi further teaches the advantage of providing variable stiffness along the length of an introducer (column 9, lines 51-54). Variable stiffness allows the introducer be sufficiently rigid to travel through a patient's vasculature but still flexible enough to allow for quick turns through torturous anatomy. The variable Zadno-Azizi is accomplished by providing the proximal region with greater stiffness than the distal region. Therefore, it would have been obvious to one of ordinary skill in the art for the reinforcing braided sheath to terminate proximal the distal end portion of the introducer. This would produce a braided sheath that terminates proximal of the balloon.

Response to Arguments

7. Applicant's arguments with respect to claims 1, 3-8, 10, 11, 17, 47, and 51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

06/03/2009

/Amy T Lang/

Examiner, Art Unit 3731

/Anhtuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

6/4/09